National Cancer Institute
Cancer Therapy Evaluation Program
Common Data Elements

Presentation to the National Cancer Institute
Cancer Biomedical Informatics Grid

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Overview

- Where we came from
  - Arising from the primordial acronym soup
- Evolution
  - Walking upright, using tools, building communities
- Where are we going
  - To infinity and beyond

NCI's Call for Standards

- "Report of the National Cancer Institute Clinical Trials Program Review Group" a.k.a. "Armitage Report"
  - August 1997
  - Call for uniform data collection
    - to promote efficient protocol implementation
    - to enhance the ability to share and compare data

NCI CTEP CDE Initiative

- Cancer Therapy Evaluation Program (CTEP) Common Data Element (CDE) initiative
  - launched in 1997
  - to standardize questions and values on case report forms (CRFs)

What is a Common Data Element?

- Standardized terms for the collection and exchange of data
- Metadata
  - attributes
  - relationships
- CTEP perspective
  - CDE represents CRF question and includes permissible values

Cancer Data Standards Repository (caDSR)

- Developed by NCICB
- Repository for NCI CDEs
- Based on *ISO/IEC 11179: Specification and Standardization of Data Elements*

Current caDSR Contexts with Common Data Elements

Context Name	# of CDEs
Cancer Therapy Evaluation Program (CTEP)	7454
caCORE	909
Specialized Programs of Research Excellence (SPORES)	619
NCI Center for Cancer Research (CCR)	548
NCI Division of Cancer Prevention (DCP)	331
Cancer Imaging Project (CIP)	213
Early Detection Research Network (EDRN)	127
Cancer Biomedical Informatics Grid (caBIG)	49
Norris Cancer Center (NORRIS)	1

Goals of CTEP's CDE Initiative

- Well-defined terminology
- Consistent data collection
- Data reduction
- Consistent analysis and meta-analysis
- Error reduction
- Data sharing

CTEP's CDE Development Process

- Collaborative committee process
- Consideration given to existing terms and standards
- Result is identification, standardization, definition, and classification of CDEs
- Mandated use on CRFs
- Identification of potential CDEs through CRF review

Current CTEP CDE Collection

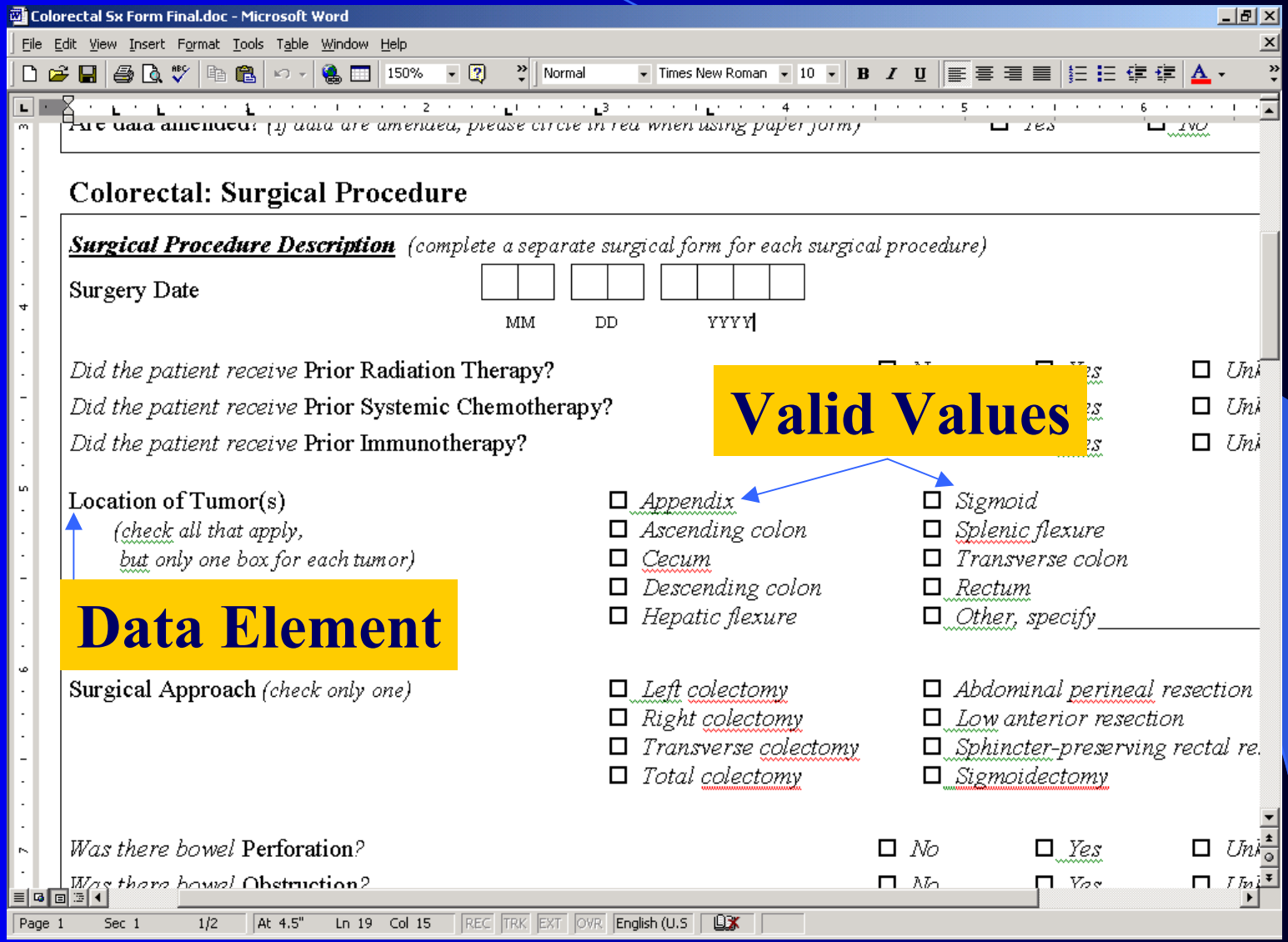
- Bladder cancer
- *Brain cancer (primary site and metastases)*
- Breast cancer
- Colorectal cancers
- Gynecologic cancers
- *Head and neck cancers*
- Leukemia
- Lung cancer
- *Lymphoma*
- Melanoma
- *Multiple myeloma*
- Prostate cancer
- *Sarcoma*
- Upper GI cancers
- Pathology
- Specimen banking

Stakeholders

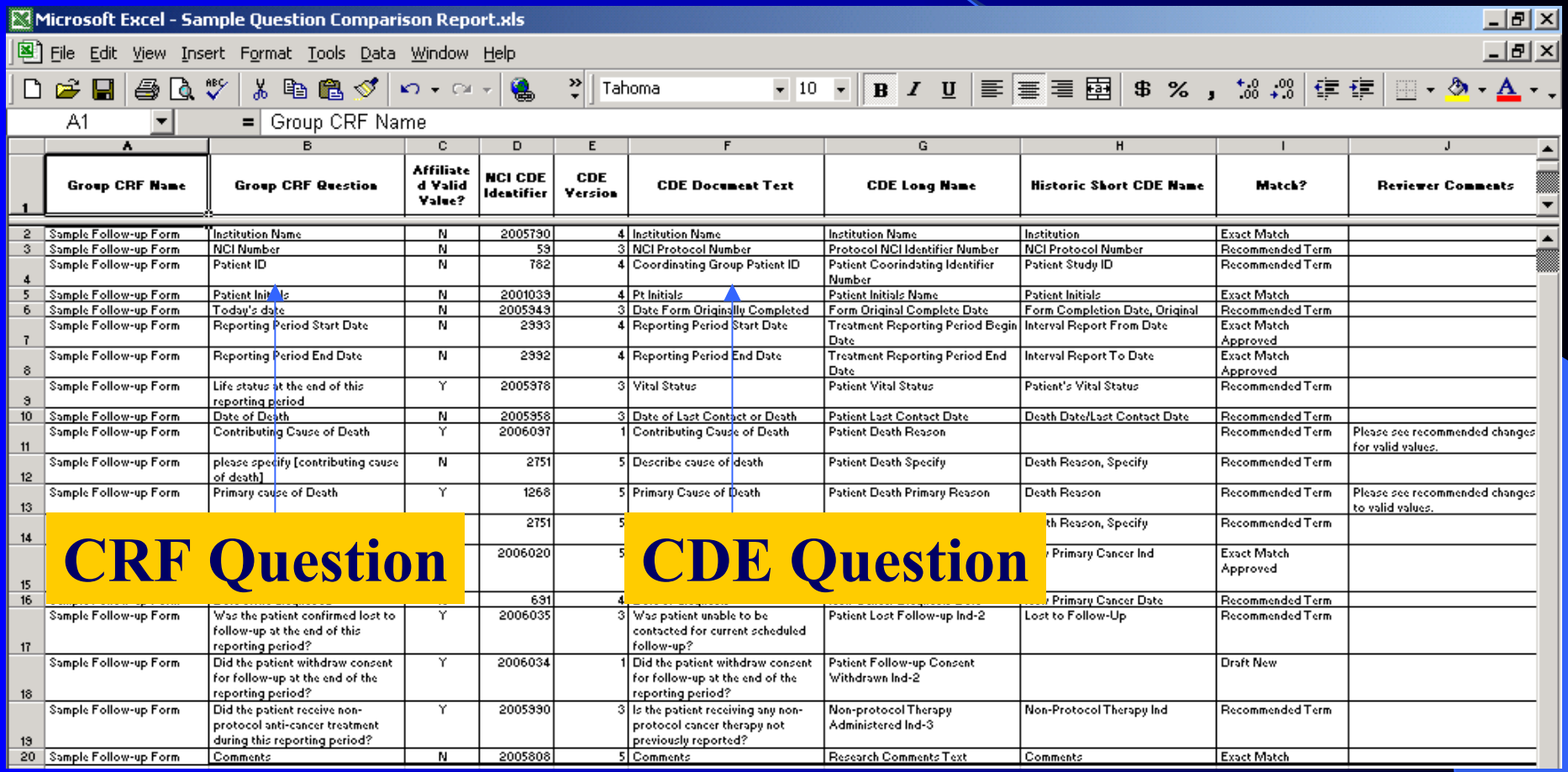
- Collaborators in development
- CTEP
- Clinical Trials Cooperative Group Program
- Specialized Programs of Research Excellence
- Cancer Biomarkers Research Group
- Early Detection Research Network
- NCI Center for Bioinformatics
- The Oracle Corporation
- The EMMES Corporation
- ScenPro

- Primary constituents
- Clinical Trials Cooperative Groups
- Cancer Trials Support Unit

Case Report Forms



Compliance Review Results

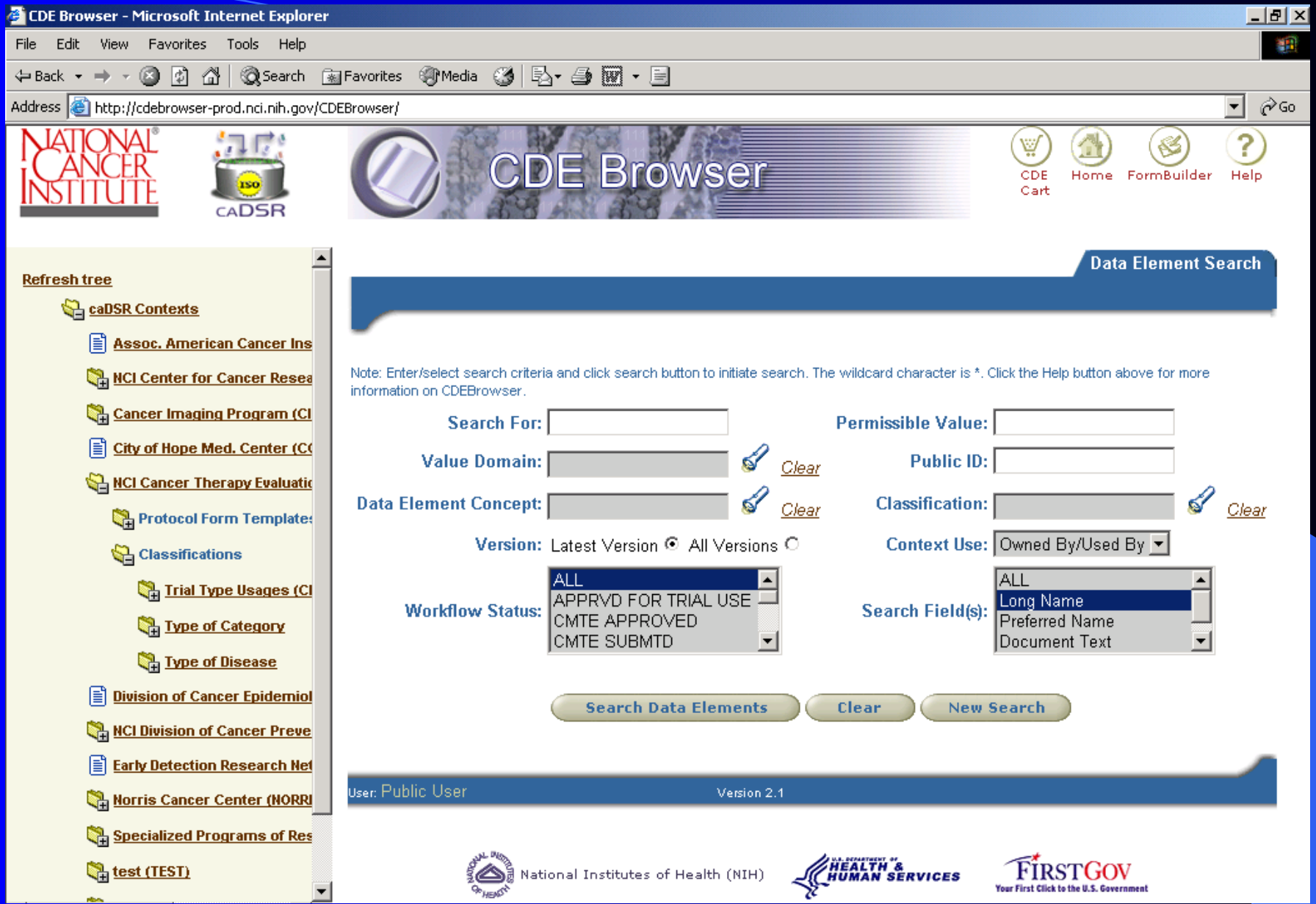


	Group CRF Name	Group CRF Question	Affiliated Valid Value?	NCI CDE Identifier	CDE Version	CDE Document Text	CDE Long Name	Historic Short CDE Name	Match?	Reviewer Comments
2	Sample Follow-up Form	Institution Name	N	2005790	4	Institution Name	Institution Name	Institution	Exact Match	
3	Sample Follow-up Form	NCI Number	N	59	3	NCI Protocol Number	Protocol NCI Identifier Number	NCI Protocol Number	Recommended Term	
4	Sample Follow-up Form	Patient ID	N	782	4	Coordinating Group Patient ID	Patient Coorindating Identifier Number	Patient Study ID	Recommended Term	
5	Sample Follow-up Form	Patient Initials	N	2001039	4	Pt Initials	Patient Initials Name	Patient Initials	Exact Match	
6	Sample Follow-up Form	Today's date	N	2005343	3	Date Form Originally Completed	Form Original Complete Date	Form Completion Date, Original	Recommended Term	
7	Sample Follow-up Form	Reporting Period Start Date	N	2393	4	Reporting Period Start Date	Treatment Reporting Period Begin Date	Interval Report From Date	Exact Match Approved	
8	Sample Follow-up Form	Reporting Period End Date	N	2392	4	Reporting Period End Date	Treatment Reporting Period End Date	Interval Report To Date	Exact Match Approved	
9	Sample Follow-up Form	Life status at the end of this reporting period	Y	2005378	3	Vital Status	Patient Vital Status	Patient's Vital Status	Recommended Term	
10	Sample Follow-up Form	Date of Death	N	2005358	3	Date of Last Contact or Death	Patient Last Contact Date	Death Date/Last Contact Date	Recommended Term	
11	Sample Follow-up Form	Contributing Cause of Death	Y	2006037	1	Contributing Cause of Death	Patient Death Reason		Recommended Term	Please see recommended changes for valid values.
12	Sample Follow-up Form	please specify [contributing cause of death]	N	2751	5	Describe cause of death	Patient Death Specify	Death Reason, Specify	Recommended Term	
13	Sample Follow-up Form	Primary cause of Death	Y	1268	5	Primary Cause of Death	Patient Death Primary Reason	Death Reason	Recommended Term	Please see recommended changes to valid values.
14				2751	5			h Reason, Specify	Recommended Term	
15				2006020	5			Primary Cancer Ind	Exact Match Approved	
16				631	4			Primary Cancer Date	Recommended Term	
17	Sample Follow-up Form	Was the patient confirmed lost to follow-up at the end of this reporting period?	Y	2006035	3	Was patient unable to be contacted for current scheduled follow-up?	Patient Lost Follow-up Ind-2	Lost to Follow-Up	Recommended Term	
18	Sample Follow-up Form	Did the patient withdraw consent for follow-up at the end of the reporting period?	Y	2006034	1	Did the patient withdraw consent for follow-up at the end of the reporting period?	Patient Follow-up Consent Withdrawn Ind-2		Draft New	
19	Sample Follow-up Form	Did the patient receive non-protocol anti-cancer treatment during this reporting period?	Y	2005390	3	Is the patient receiving any non-protocol cancer therapy not previously reported?	Non-protocol Therapy Administered Ind-3	Non-Protocol Therapy Ind	Recommended Term	
20	Sample Follow-up Form	Comments	N	2005808	5	Comments	Research Comments Text	Comments	Exact Match	

caDSR Tools of the Trade

- CDE Browser
- http://ncicb.nci.nih.gov/CDEBrowser/

- caDSR Administration Tool
- Curation Tool
- CDE Compliance Review Tool
- CRF CDE Review Response Tool



http://ncicb.nci.nih.gov/cdebrowser/

Version 2.1

- *Released May 28, 2004*
- *CDE Cart*
- *Form Builder*
- *caDSR web site*
  - http://ncicb.nci.nih.gov/core/caDSR
- *caDSR Users Listserv*
  - http://list.nih.gov/archives/cadsr_users.html
- *CTEP Documentation*
  - http://ncicb.nci.nih.gov/NCICB/core/caDSR/CTEPInformation

Status of CTEP CDE Initiative

- *2400 approved CDEs*
  - *CTCAE v3.0*
  - *CDUS v3.0, release 2*
- *3200 terms awaiting review*

- Phase III studies
- Adult trials
- Clinical Trials Cooperative Groups
- Cancer Trials Support Unit

Future CTEP CDE Development

- *Quality of life*
- *Eligibility criteria*
- *Phase I and II trials*
- *Pediatric studies*

Harmonization

- *Business rules*
- *CDEs*
- *Training*

- *Registration status*

In Conclusion